

### **REMARKS**

Claims 1-15 are cancelled.

Claims 16-26 are pending.

Claims 16-26 are rejected.

Claim 16 is amended. Support for the amendment is found in the paragraph bridging pages 4-5.

### **CLAIM REJECTION – 35 U.S.C. § 103**

**Claims 16-18 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley (U.S. Patent No.: 5,415,629).**

**Claims 19–24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley (U.S. Patent No.: 5,415,629), as applied to claims 16-18 and 25 above and in further view of Hansson (U.S. 2004/0191322).**

Applicants claimed invention combines a first nicotine administration part that provides a continuous dose of nicotine with a second nicotine administration part activatable by the user that provides additional nicotine for short term craving relief.

In contrast to Applicants' two-part patch for nicotine, Henley teaches a one-part patch for the pain killer Fentanyl®, being a passive patch that is combined with a programmable ionosonic or iontophoretic drug delivery apparatus. In the paragraph bridging columns 5 and 6 Henley suggests that such an apparatus could be used to "improve the current management of pain/drug substance detoxification and many other illnesses currently managed by injections and repeated dosing of drugs". In that same paragraph, Henley states that "Although many of the foregoing applications presented herein are possibilities for future technologies, the present invention addresses a

currently critical social problem by providing an effective, wearable, intelligent apparatus and method for the management of drug and substance abuse addition”.

At best, this is an invitation to experiment but does not in fact suggest a nicotine delivery device with two parts that provide continuous and additional dosing of nicotine. The first teaching in Henley of the use of nicotine is at column 4, lines 3-9 and is also repeated at column 6, lines 49-57. These teachings utilize the “tingling sensation” of Henley’s device to help a patient receive an ever-decreasing dose of nicotine. That would not be possible with Applicants’ claimed invention which has a continual dose via the first part and extra nicotine provided by the activatable second portion. The next teaching in Henley of a nicotine device is in column 4, lines 51 through 59. That teaching is “for the release of nicotine on a preprogrammed basis, permitting the additional release of nicotine when the patient quitting smoking faces an unusual craving situation”. This is also significantly different from Applicants’ claimed invention which includes a portion that is not preprogrammed but is continuous. And, the other portion of the Applicants’ claimed invention is not a preprogrammed device, but a device that is activatable by the user.

Applicants respectfully disagree with two points in the previous Office Action. First, the Office Action states that Applicants recognize that Henley suggests the combination of a first nicotine administration part with a second nicotine administration part. Applicants do not recognize this, nor did they in the previous response. In fact, it is Henley’s lack of such a suggestion that renders the claimed invention patentable.

Second, Applicants maintain that Henley teaches away from the claimed invention. Contrary to the assertions in the Office Action the teachings of Henley are not mere alternative embodiments. The entirety of Henley’s teaching is to provide a device to reduce the amount of active ingredient being delivered to the user. One of ordinary skill, reading Henley in its entirety, would not be motivated to make a device that provides continuous nicotine administration and additional, user controlled nicotine

administration because such a device is contrary to the goals and solutions taught by Henley.

As amended, Applicants invention is structurally different and not suggested by Henley. Henley's broad teaching of combining a passive patch with a programmable device does not render obvious Applicants claimed invention.

Regarding the combination of Henley with Hansson, Hansson only teaches that certain forms of nicotine may be administered transdermally. This teaching does not relate to either the function or the structure of the claimed device. Therefore the teaching of Hansson does not make up the deficiency in Henley and their combination fails to teach or suggest the claimed invention.

Accordingly, Applicants respectfully submit that the rejection of claims 16-18 and 25-26 under 35 U.S.C. 103a under Henley and claims 19-24 under Henley in view of Hansson are improper and should be withdrawn.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the number listed below.

Respectfully submitted,

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